



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,861	12/26/2001	Hai Xing Chen	99,003.1	4882
7590	09/30/2004		EXAMINER	
CUSPA Technology Law Associates 11820 SW 107 Ave. Miami, FL 33176				CHUNDURU, SURYAPRABHA
		ART UNIT	PAPER NUMBER	1637

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,861	CHEN, HAI XING	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 July 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-25 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicants' response to the office action filed on July 14, 2004 has been entered.
2. Claims 1, and 14 are amended. Claims 1-25 are pending. Non-elected claims 26-29 are withdrawn from consideration in view of restriction/election.

Response to arguments

4. Applicants' response to the office action is fully considered and found persuasive in part..
5. With reference to the rejections made in the previous office action under double-patenting Applicants' amendment and arguments are fully considered and are found not persuasive. Applicants argue that the instant amended claims are patentably distinct and are not obvious over the US patents 6,714,733 ('733) and 6,337,214. Applicants also argue that these patents disclose detecting more than one DNA sequence by binding different DNA sequences to different snares and detecting different sequences on different snares and do not disclose detecting different DNA sequences on the same snare and therefore are patentably distinct and are non-obvious. Applicants' arguments are fully considered and found not persuasive. The patented claim 7 in the patent '733 discloses a snare comprising two different nucleic acid sequences on the same snare (one sequence for control and another sequence for negative control), which encompasses the limitation s of the instant claims. Likewise in the patent '214, the patented claim 9 discloses two different sequences on the same snare. Thus the instant claims are not patentably distinct and the rejections are maintained herein.

With regard to the double patenting rejection in view of Lee et al., Applicants' arguments are fully considered and found not persuasive. As discussed above the patented claims encompass the limitations of the instant claims and it is obvious to modify the method with the inclusion of a

non-radioactive label for the advantage of reducing the use of hazardiuos radioactive labels and to increase the sensitivity of the assay. Thus the rejections are maintained herein.

6. With reference to the rejection made in the previous office action under 35 USC 102(e), Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment and new grounds of rejection.

7. With reference to the rejection made in the previous office action under 35 USC 103(a), Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment and new grounds of rejection.

New Grounds of Rejections necessitated by amendment

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wainwright et al. (USPN. 5,876,918) in view of Bohannon (USPN. 6,261,771).

Wainwright et al. teach a method of claims 1, 7, 18, 24, for detecting multiple test materials in a test sample comprising (a) adding a test sample in to a column (tip) having a plurality of snares (layers) (see col. 5, line 52-61, col. 9, line 43-51), of said snares one snare being a test snare having at one target capture materials a first target capture material (a biotinylated alkaline phosphatase (BAP) attached DNA fragment) (see col. 9, line 43-46) and another snare having control DNA (see col. 9, lines 49-61).

(b) washing said column to remove unbound test materials (see col. 9, line 51-57);

(c) adding a probe with a chemical label (streptavidin) that specifically binds to the said first test material (see col. 9, line 55-61);

(h) detecting signals generated by said first and second test materials (see col. 9, line 55-61).

With regard to claims 3, 6, 8, 15-16, 25, Wainwright et al. also teach said labels are chemiluminescence labels (BAP) (see col. 9, line 43-61); test material comprises DNA (see col. 9, line 55-61);

With regard to claims 10-13, 19-23, Wainwright et al. also teach said method comprises a positive and negative controls (see col. 9, line 47-61);

With regard to claim 14, Wainwright et al. teach that said method comprises a plurality of snares (layers) (see col. 5, line 52-61, col. 9, line 43-51).

However, Wainwright et al. did not teach plurality of capture material on the same snare.

Bohannon teach a method of claims 1-25 for detecting multiple target nucleic acid sequences in a sample using a tube (snare) comprising beads with different oligonucleotides (indicates more than two probes with regard to claims 7, 18 and different probes for different target sequences) and plurality of beads are placed in a known order in a tube (see col. 11, lines 13-37). Chemical labels include Ruthenium or Osminum labels (see col. 5, line 42-52).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting a target nucleic acid using different snares as taught by Wainwright et al. with the step of adding multiple binding elements on the same snare as taught by Bohannon to achieve expected benefit of developing an enhanced and

improved method for detecting multiple target sequences in a sample because Bohannon taught that the method of detecting multiple target sequences simultaneously, would reduce the contamination of reaction mixture and provide automation of the technique. In order to reduce contamination and develop a high throughput technique, an ordinary practitioner would have been motivated to modify the method of detecting a target nucleic acid as taught by Wainwright et al. by incorporating the incorporation of multiple binding elements on the same snare to develop a method that would provide detection of multiple targets in a sample at a given time.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

SP
Suryaprabha Chunduru
September 29, 2004

JF
JEFFREY FREDMAN
PRIMARY EXAMINER

JWF